

**REMARKS**

**I. Status of Claims**

Currently, claims 1, 3, 10-12, 14, 20, 22-24, 26, and 30-51 are pending in this application, claims 23-24, 26, and 30-35 having been withdrawn by the Office as directed to a non-elected invention.

By this amendment, Applicants propose to amend claims 1, 12, 36, 40, 44, 48, 49, and 50 to recite that the “second enzyme is the wild type Pfu DNA polymerase comprising the amino acid sequence of SEQ ID NO. 12 identified at Accession No. P80061 . . .” Support for this amendment can be found throughout the specification, including, for example, at page 25, lines 14-17, which incorporates by reference, *inter alia*, U.S. Patent No. 5,948,663 (“the ‘663 patent”). The ‘663 patent discloses the amino acid sequence of the wild type Pfu DNA polymerase (i.e., SEQ ID NO. 1). Applicants have also amended the specification to include the wild type Pfu DNA polymerase sequence and submits with this response a substitute sequence listing including the wild type Pfu DNA polymerase sequence (SEQ ID NO. 12). This amendment does not narrow the scope of the pending claims.

Applicants also propose to amend claims 48-50 to recite that the wild type Pfu DNA polymerase is “mutated ~~in at least one~~ an amino acid ~~position~~ selected from the group consisting of: . . . , or combinations thereof, . . . .” Support for this amendment can be found throughout the specification, including, for example, at page 7 and in the claims, as originally filed. This amendment does not narrow the scope of the pending claims.

The proposed amendments do not introduce new matter.

Applicants respectfully request that the Examiner enter this Amendment under 37 C.F.R. § 1.116, placing the pending claims in condition for allowance or better form for appeal. Applicants submit that the proposed amendments do not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. This Amendment should, therefore, allow for immediate action by the Examiner.

## **II. Discussion with Examiner Hutson**

Applicants would like to thank Examiner Hutson for taking the time to discuss the instant application with Applicants' representative (the undersigned attorney) on 18 September 2008. The substance of the discussions that took place September 18 is discussed below.

## **III. Rejection Under 35 U.S.C. §112, Second Paragraph**

The Office rejects claims 1, 3, 10, 11, 12, 14, 20, 22, and 36-51 under § 112, second paragraph as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter that applicants regard as the invention. Office Action at page 2. In the previous Office Action, the Office asserted that “[r]eference to Y410, T542, D543, K593, Y585, Y385, G387 and G388 is a relative to an amino acid sequence and absent a reference amino acid sequence such reference is indefinite.” Office Action mailed 19 February 2008, at pages 2-3. Because the wild type Pfu DNA polymerase was known as of the filing date of the instant application, Applicants argued that it was not necessary to recite the actual sequence or an accession number in the claims because one of skill in the art would understand the metes and bounds of the claim. Nevertheless, in the response filed 19 May 2008, solely in an effort to

expedite prosecution, Applicants amended claims 1, 12, 36, 40, 44, 48, 49, and 50 to recite that second enzyme is the “wild type Pfu polymerase identified at Accession No. P80061 . . ..”

In response, the Office asserts that “reference to an ‘Accession No.’ is considered to be ‘essential material’ . . . necessary to describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112.” Office Action at page 4. Applicants respectfully disagree. In fact, in a similar context, the Federal Circuit has held that requiring an applicant to recite known DNA structures is at odds with the goals of the written description requirement:

Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention. As we stated in *Capon*, “[t]he ‘written description’ requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.” *Id.* at 1358. Indeed, the forced recitation of known sequences in patent disclosures would only add unnecessary bulk to the specification.

*Falko-Gunter Falkner v. Inglis*, 448 F.3d 1357, 1368 (Fed. Cir. 2006).

For the same reasons, requiring an applicant to recite a known polypeptide sequence is at odds with the requirements of 35 U.S.C. §112, second paragraph because one of skill in the art would understand the metes and bounds of the *known* wild type Pfu DNA polymerase sequence recited in the claims without reciting the actual amino acid sequence or otherwise referring to an Accession number corresponding to the known sequence. Thus, the actual amino acid sequence or a reference to Accession No. P80061 (corresponding to the known sequence) does not

constitute essential matter because under the facts presented here neither is required to comply with 35 U.S.C. §112.

Nevertheless, solely in an effort to expedite prosecution and without acquiescing to the Office's rejection, Applicants have amended the claims to recite that the wild type Pfu DNA polymerase comprises the amino acid sequence of SEQ ID NO. 12. As noted above, this sequence corresponds to SEQ ID NO. 1<sup>1</sup> of the '663 patent, which is incorporated by reference at page 25 of the specification.

Applicants' representative spoke with Examiner Hutson about this rejection on 18 September 2008 and proposed amending the claims to recite the amino acid sequence of the wild type Pfu DNA polymerase disclosed in the '663 patent. Examiner Hutson agreed that the specification appeared to support the incorporation of the Pfu wild type sequence from the '663 patent and indicated that amending the claims, as proposed, would be viewed favorably and, subject to a final review, should obviate this 35 U.S.C. §112, second paragraph rejection. Accordingly, Applicants respectfully request that the Office withdraw this rejection.

#### **IV. Rejection of Claims 48-51 Under 35 U.S.C. § 112, First Paragraph**

The Office rejects claims 48-51 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and as lacking enablement. (Office Action at pages 8-11.) In contrast to the clear language and meaning of the claims, in setting forth the rejection, the Office has parsed the phrase "at least one amino acid position selected from the group consisting of" into two separate and distinct phrases: "at least one" and "amino acid

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<sup>1</sup> SEQ ID NO. 1 of the '663 patent has the same amino acid sequence as the sequence identified at Accession No. P80061.

position selected from the group consisting of.” Specifically, the Office interprets the phrase “at least” in the context of claims 48-50 “as allowing additional mutations outside the referenced positions, such that applicants have not adequately described [or enabled] this genus.” Office Action at page 8.

Applicants disagree with the Office’s interpretation for the reasons of record. Nevertheless, in an effort to expedite prosecution, and not in acquiescence to the Office’s rejection, Applicants have amended claims 48-50<sup>2</sup> to recite the wild type Pfu DNA polymerase is “mutated ~~in~~ at ~~least one~~ an amino acid ~~position~~ selected from the group consisting of: . . . , or combinations thereof, . . . .”

The present claim language, and in particular the phrase “or combinations thereof,” indicates to those of skill in the art that the genus described by the “Markush” group is not limited to enzymes with a single mutation, but rather is directed to enzymes having a single mutation or any combination of mutations selected from the recited group. The claims clearly indicate which mutation or mutations are within the literal scope of the group from which mutations may be selected.

As the Federal Circuit has recognized, a patent applicant may expressly indicate that a claim covers a combination of the recited Markush members by using language such as “and mixtures thereof” or “at least one member” in the Markush group. That is precisely what Applicants have done here. As noted in *Abbott Labs. v. Baxter Pharmaceutical Prods., Inc.*, 334 F.3d 1274, 1281, (Fed. Cir. 2003), “[i]f a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while

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<sup>2</sup> Claims 51 depends from claims 48, 49, and 50.

drafting the claim.” Citing to the “Meeting Held to Promote Uniform Practice In Chemical Divisions,” 28 J. Pat. & Trademark Off. Soc’y 849, 852 (1946), the Federal Circuit recognized examples of qualifying language in Markush groups that was approved by the USPTO, including “and mixtures thereof” and “at least one member of the group.” *Id.* Thus, as acknowledged by the Federal Circuit, it has long been common practice to use expressions like “combinations thereof” in the context of Markush language to indicate that the claim covers one or more members of the recited Markush group.

For at least this reason, Applicants request that the Office reconsider and withdraw the rejection of claims 48-51 under 35 U.S.C. § 112, first paragraph.

**V. Double Patenting Rejections**

The Office provisionally rejects claims 1, 3, 10-12, 14, 20, 22, and 36-51 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 64-70 and 75-87 of copending U.S. Patent Application No. 10/079,241. (Office Action at pages 12-13.) Applicants acknowledge this provisional rejection and request that the Office hold the rejection in abeyance until one or the other application is in condition for allowance. At that time, Applicants will file a Terminal Disclaimer in the application that has yet to be allowed, if necessary at that time.

**VI. Conclusion**

Applicants believe that this application is in condition for allowance. If the Office believes anything further is required in order to place this application in even better condition for

allowance, Applicants request that their undersigned representative be contacted at the number listed below to discuss remaining issues.

Please grant any extensions of time required to enter this paper and charge any additional required fees to Deposit Account No. 50-3740.

Respectfully submitted,  
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